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10/532,698	04/26/2005	Nicolai Agger	P07181US00	8742
22885	7590	08/28/2008	EXAMINER	
MCKEE, VOORHEES & SEASE, P.L.C.			CLARK, AMY LYNN	
801 GRAND AVENUE				
SUITE 3200			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,698	AGGER, NICOLAI	
	Examiner	Art Unit	
	Amy L. Clark	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 April 2008.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2,5-11 and 13-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,5-11 and 13-23 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on 23 April 2008 with the amendment of claims 1, 2, 9 and 23.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 5-11 and 13-23 are currently pending and currently under examination.

Response to Amendment

The declaration filed on 04/23/2008 under 37 CFR 1.131 has been considered but is ineffective to overcome 35 U.S.C. 103(a) reference. Newly applied as necessitated by amendment.

Applicant's declaration states that a synergistic effect exists between psyllium and L-glutamine for cell growth; however, first of all Applicant's claims, as written, do not recite the specific combination of psyllium and L-glutamine, nor are the claims drawn to the effect of cell growth, which is currently also not enabled. Secondly, Applicant declares that this effect has been disclosed in the originally filed specification and directs attention to the following PreGrant publication paragraph (0061), wherein Applicant discloses, "It has quite unexpectedly been found that the addition of an agent comprising a rehydrant containing Isphagula Husk and a mixture comprising amino acids to a cell culture enhances cell growth significantly compared to adding either the rehydrant containing Isphagula Husk alone to the cell culture or a rehydrant without

Ispaghula Husk and the mixture to the cell culture". This in no way supports the specific combination of psyllium and L-glutamine, nor does it support the idea of a synergistic effect. Synergism is an unpredictable phenomenon which is highly dependent upon specific proportions and/or amounts of particular ingredients. Accordingly, the recitations of the amounts ranges and/or proportions (e.g., ratios) of each claimed ingredient necessary to provide a synergistic combination is deemed essential (see, e.g., MPEP 2172.01) and, are not currently defined in the independent claim language itself. While Applicant has recited the weight % (although the recited weight percentages are not related to a determined parameter of mass or volume) of each of the claimed ingredients in claims 1 and 2, the Office notes that as drafted claim 1 reads "A composition for the treatment of diarrhea of monogastric animals comprising 5-30% by weight Ispaghula husk (*Plantago ovata*), from 1-20% by weight of at least one amino acid and from 20-80% by weight of a mixture of at least one carbohydrate and at least one electrolyte" and claim 2 is drawn to a method of using this composition, wherein the composition is used to treat diarrhea of monogastric animals. As drafted, claims 1 and 2 would appear to not read on a synergistic herbal insecticidal formulation, since synergism is generally defined by the enhanced overall activity of more than one ingredient when combined together as compared to the overall activity of each of the ingredients alone. Therefore, part 1.) of Applicant's declaration is not commensurate with the scope of the claims, nor is their support for Applicant's assertion in Applicant's originally filed specification.

In response to Applicant's declaration provided in part 2.) with regards to the combination of psyllium and L-glutamine, since this specific combination of ingredients was not claimed (again, claims 1 and 2 are drawn to composition for the treatment of diarrhea of monogastric animals comprising 5-30% by weight Isphagula husk (*Plantago ovata*), from 1-20% by weight of at least one amino acid and from 20-80% by weight of a mixture of at least one carbohydrate and at least one electrolyte and its use, which is not the same as a composition comprising psyllium and L-glutamine), it is unclear as to whether art exists with regards to this specific combination of ingredients, since the entire composition comprising what was claimed was searched.

In response to Applicant's graph in part 3.), which was provided by Applicant to illustrate the synergistic effect on cell growth, it is unclear as to what each ingredient is (what is "WHO" comprised of? Applicant states that is the "old formulation" with no amino acid, but does not disclose what Applicant regards as the "old formulation" or what the WHO composition with the amino acid comprises). Secondly, the graph is hard to decipher because all of the labels are similar on the plot and the graph is in black and white, so it is hard to make out which line belongs to which label.

Therefore, the declaration does not overcome the references cited in the previous Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Newly applied as necessitated by amendment.

The claim as set forth in the amendment filed 23 April 2008 contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

In the amended Claim 9, Applicant claims, “a composition according to claim 1, wherein the at least one amino acid is obtained from a lactic yeast source”, thereby introducing the new limitation “wherein the at least one amino acid is obtained from a lactic yeast source”, which is considered to be new matter. Insertion of the above mentioned claim limitation has no support in the as-filed specification. The insertion of the limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept “a composition according to

claim 9, wherein the at least one amino acid is obtained from a lactic yeast source".

The specification, as originally filed, discloses, a mixture of amino acids according to the invention may be provided from lactic yeast ("Milchhefe") that has been processed to provide the soluble components of the yeast cells. The specification, as originally filed, further discloses, at least one amino acid is comprised in a yeast extract, where the yeast is lactic yeast and processed lactic yeast is preferably supplemented with glutamine (paragraphs 0032-0034 in the PreGrant publication). This is not sufficient support for the new genus: "a composition according to claim 9, wherein the at least one amino acid is obtained from a lactic yeast source". This is a matter of written description, not a question of what one of skill in the art would or would not have known.

The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of the above mentioned claim-limitation is considered to be the insertion of new matter for the above reasons.

As the above- mentioned claim limitation could not be found in the present specification, the recitation of the claim limitation is deemed new matter; and, therefore it must be omitted from the claim language, unless Applicant can particularly point to the specification for literal support.

Response to Arguments

Claim Rejections - 35 USC § 112

Claim 9 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is maintained for reasons of record set forth in the paper mailed on 10 January 2008 and repeated below, slightly altered to take into consideration Applicant's amendment filed on 23 April 2008.

Applicant's arguments have been thoroughly considered, but the rejection remains the same for the reasons set forth in the previous Office action and for the reasons set forth below.

The metes and bounds of Claim 9 are rendered uncertain by the phrase "obtained from a lactic yeast source" because, first of all, it is unclear as to what Applicant means by "lactic yeast source". Does Applicant mean that the source is lactic yeast or does Applicant mean that the amino acid is obtained from a source of lactic yeast? Is that the medium on which the yeast is grown or does that mean the lactic yeast itself? Also, what does Applicant mean by "lactic yeast"? Does Applicant mean that yeast is grown on milk or that the yeast produces lactic acid? What is a lactic yeast source? The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

Applicant argues that the amendment overcomes the 112 2nd rejections; however, this is not persuasive because Applicant regards as a "lactic acid source".

Claim Rejections - 35 USC § 103

Claims 1, 2, 5-11 and 13-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gjerløv (N*, WO 85/01441 A1), in view of Simone (A*, US Patent Number: 5,397,786), "Always your Choice: Diarrhea-Nutritional Management" (U*), http://web.archive.org/web/*/http://www.gatorade.com/ (V*) and Nakagaki (O*, JP 08-038046 A).

This rejection is maintained for reasons of record set forth in the paper mailed on 10 January 2008 and repeated below, slightly altered to take into consideration Applicant's amendment filed on 23 April 2008.

Applicant's arguments have been thoroughly considered, but the rejection remains the same for the reasons set forth in the previous Office action and for the reasons set forth below.

Gjerløv teaches a specific composition for both rehydrating a monogastric animal and which stops diarrhoea (which is an alternative spelling of diarrhea) comprising glucose, citric acid, potassium chloride, sodium citrate, sodium chloride, sodium bicarbonate (which are all electrolytes), terra rubrum, which is a coloring agent, wheat bran, which is a filler and is a fibrous bran material, and Isphagula husk, which is the dried seed coats of *Plantago ovata* (See page 11 and also page 12, Examples 1 and 2). Gjerløv further teaches the composition may comprise electrolytes in an amount of 40-

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60% by weight, fibre (which is an alternative spelling of fiber) from dried, crushed seed coats of *Plantgo ovata*, which is synonymous with Isphagula Husk, in an amount of 20-70% by weight, fillers (roughage), such as fibrous wheat bran, taste corrigents and coloring agents (See abstract), and that the composition should be administered in the form of a beverage (See page 11 and also page 12, Examples 1 and 2). Please note that electrolytes, by definitions, replace salts lost by the body through excessive fluid loss (such as via vomiting, sweating, diarrhea, etc.).

Simone teaches a rehydration drink for people who work under severe conditions, are athletes and patients who exhibit dehydration from diarrhea or vomiting, comprising 1-35 milligrams of at least one carbohydrate, such as glucose (See column 2, lines 45-48, 64 and 65), electrolytes in an amount of 2 to 2500 milligrams, such as sodium chloride and potassium chloride (See column 3, lines 5 and 9), at least one ammonia neutralizer, in the form of an amino acid, in an amount of 0.1 to 750 milligrams, such as glutamine (See column 3, lines 21-28), and at least one antioxidant, such as vitamin E (See Abstract). Please note that electrolytes, by definitions, replace salts lost by the body through excessive fluid loss (such as via vomiting, sweating, diarrhea, etc.).

“Always your Choice: Diarrhea-Nutritional Management” teaches that Gatorade is a fluid and electrolyte replacement supplement that works well for people with diarrhea (See page 1). “Always your Choice: Diarrhea-Nutritional Management” further teaches that glutamine is an amino acid that gets used up during gastrointestinal distress and

that adding glutamate back to the gut helps feed the gut cells and repair damage, thereby helping with digestion and absorption (See page 3).

http://web.archive.org/web/*/http://www.gatorade.com/ teaches that Gatorade contains glucose-fructose syrup, sodium citrate, citric acid (both are electrolytes) and Red 40, which is synonymous with FD&C RED #40, and is a known food coloring agent.

Nakagaki teaches a spawn for fermented milk and fermented milk produced by the spawn, wherein the span comprises a yeast fungus and wherein the fermented milk, which reads on a lactic yeast source, prevents and treats diarrhea.

Although Nakagaki does not teach that an amino acid, such as glutamine, is obtained from a lactic yeast source, the claimed functional properties are intrinsic to the preparation taught by Nakagaki because the ingredients taught by Nakagaki are one and the same as disclosed in the instantly claimed invention of Applicant and because glutamine is prevalent in milk and milk is known to be a good source of glutamine. Therefore, the fermented milk taught by Nakagaki intrinsically contains glutamine and glutamine would thereby be intrinsic to milk fermented with lactic yeast.

Gjerløv does not teach that a composition comprising Isphagula husk, at least one carbohydrate and electrolytes further comprises at least one amino acid, such as glutamine, nor does Gjerløv teach an amino acid processed form a lactic yeast source, nor does Gjerløv teach a composition further comprising alpha tocopherol (vitamin E). However, at the time the invention was made, it would have been obvious to one of ordinary skill in the art and one would have been motivated and had a reasonable expectation of success to modify the composition taught by Gjerløv to provide the

instantly claimed invention because at the time the invention was made it would have been obvious to combine the ingredients of a composition for rehydrating monogastric animals and for stopping diarrhea, which reads on treating diarrhea, suffering from diarrhea, including human beings, wherein the composition comprises glucose, citric acid, potassium chloride, sodium citrate, sodium chloride, sodium bicarbonate (which are all electrolytes), terra rubrum, which is a coloring agent, wheat bran, which is a filler and is a fibrous bran material, and Isophogla husk, which is the dried seed coats of *Plantago ovata*, taught by Gjerlov, with amino acids, such as glutamine, and at least one antioxidant, such as vitamin E taught by Simone, ingredients found in Gatorade, such as glucose-fructose syrup, sodium citrate, citric acid (both are electrolytes) and Red 40, which is synonymous with FD&C RED #4 and also glutamine because glutamine is an amino acid that gets used up during gastrointestinal distress and that adding glutamate back to the gut helps feed the gut cells and repair damage, as taught by "Always your Choice: Diarrhea-Nutritional Management" and http://web.archive.org/web/*//http://www.gatorade.com/ and it would have been obvious to use fermented milk, which reads on a lactic yeast source, because fermented milk is known to prevent and treat diarrhea, as taught by Nakagaki. Furthermore, one of ordinary skill in the art would have reasonable expectation of success in using such a composition for treating diarrhea and rehydrating a monogastric animal suffering from diarrhea because the beneficial properties of the claimed ingredients for this purpose are taught by the cited references.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add any of the claimed ingredients in the making of the claimed composition because it is well known that its *prima facie* obvious to combine two or more ingredients, each of which is taught by the prior art, to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based upon the beneficial teachings of the cited references, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Applicant argues that Gjerlov does not teach the amino acid preferably accessed from the lactic yeast source and does not teach a composition that further comprises alpha-tocopherol. Applicant further argues that Gjerlov fails to teach anything about synergism that is the basis of the present Application and that absence of any teaching of the synergistic effect of psyllium and L-glutamine (or other amino acid) on cell growth, thereby rendering the invention unobvious due to the unexpected result.

In response to applicant's arguments, first of all, the Examiner has established a

prima facie case of obviousness by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Examiner has provided motivation to combine the ingredients claimed by Applicant, since all of the ingredients were known at the time the invention was made to have the same functional effect as that claimed by Applicant.

Secondly, with regards to Applicant's argument regarding synergism, please see the Examiner's arguments above regarding synergism, wherein the Examiner argues that Applicant's claims, as written, do not recite the specific combination of psyllium and L-glutamine, nor are the claims drawn to the effect of cell growth, which is currently also not enabled and that synergism is an unpredictable phenomenon which is highly dependent upon specific proportions and/or amounts of particular ingredients (See "Response to Amendment" regarding the declaration filed on 04/23/2008 under 37 CFR 1.131).

Finally, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a

reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy L. Clark
AU 1655

Amy L. Clark
July 28, 2008

/Michele Flood/
Primary Examiner, Art Unit 1655